



Section: 800 – Office of Research Administration

Subject: Innovative Therapy Guidelines

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I. Purpose

Jackson Health System (JHS) recognizes that healthcare providers may be presented with situations where an innovative therapy or intervention is in the best interests of a particular patient. This Policy is intended to help JHS Leadership and physicians understand the difference between innovative practice and actual research and apply the guidelines/requirements as appropriate.

II. Definitions

Adverse event (AE): any untoward or unfavorable medical occurrence in a human subject, including any abnormal physical exam or laboratory findings, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Important Medical Events (IME): that may not result in death, be life threatening, or require hospitalization may be considered as serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in 21 CFR 312.32(a).

Innovative Therapy: is a newly introduced or modified therapy with unproven effect or side effect and is undertaken in the best interest of the patient and not designed to test hypothesis. Innovative care may be proposed as an intermediary step between clinical care and formal research. Innovative Therapy is intended to cover a very limited number of patients (usually one and no more than three) in whom unusual, innovative approaches are used for the primary goal of clinical diagnosis or therapy. It is not intended to be an emergency use of an investigational device or drug.

Serious Adverse Events (SAE): the Office of Human Research Protections Guidance defines an SAE as any adverse event that:

1. Results in death;



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2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. Results in inpatient hospitalization or prolongation of existing hospitalization;
4. Results in a persistent or significant disability/incapacity;
5. Results in a congenital anomaly/birth defect; or
6. Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization).

III. Procedure

- A. Considerations of a Proposed Innovative Intervention or therapy
 1. Reflects significant changes in clinical procedures, technology, techniques, devices and treatment therapy (involving more than a gradual change)
 2. Has not yet been introduced at the hospital, but has been utilized elsewhere at another medical institution
 3. Has cost implications or impact on institutional resources and personnel and/or
 4. Poses sufficient risk that independent review would be beneficial to the patient, healthcare professional or staff person, particularly to prevent, and in the event of an adverse outcome.
- B. Application of Innovative Interventions or Therapies
 1. Innovative interventions may be employed when standard approaches have failed or when no standard treatment is known and there is evidence elsewhere that the novel therapy may have efficacy.
 - a. In such cases it may be administered on an emergency basis and attempted with only a few patients, often referred to as "compassionate" treatment.
 2. Innovative therapy may also be proposed for the use of a device that is inconsistent with the Food and Drug Administration (FDA)-approved label such as for a different population or for a different indication, and in which the intent is strictly clinical.
- C. Obtain Approval
 1. The healthcare provider proposing an intervention for a particular patient, which is not currently the standard of practice at JHS, provides the evidence supporting the use of the intervention for the particular patient to their department head.
 - a. The evidence may be research based or information on the standard of practice at peer institutions.
 2. The department head, in conjunction with clinical leadership for the other health care disciplines involved, assesses the risks and possible benefits associated with the intervention for the patient, provider/s, and the institution, and determines whether the intervention or procedure is innovative or research.
 - a. If the proposed intervention has a primary intent of creating new knowledge, the approach is more suitable to clinical research or expanded access as described in 21 CFR 312.300, and not an innovative intervention.
 3. Once it has been determined that the proposed intervention is innovative, the healthcare provider proposing the intervention or treatment submits the proposed innovative



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intervention to the Chief Medical Officer (CMO) and Chief Financial Officer (CFO) for review and approval before the intervention is scheduled.

- a. The healthcare provider presents a letter co-signed by the division chair that includes:
 - i. A description of the clinical situation.
 - ii. The planned innovative diagnostic or therapeutic approach to treating or diagnosing the disease or condition.
 - iii. A description of the expected risks of the intervention reviewed and amended with all involved care providers.
 - iv. A plan of care describing the projected needs of the patient post-innovative intervention and an outline of the plan for monitoring the outcomes of the proposed intervention.
 - v. Justification for determining that other standard therapies are not appropriate to the needs of this patient.
 - vi. A full discussion of how the benefits of the intervention outweigh the risks.
 - vii. A rationale for determining that the approach is an innovative intervention rather than a pilot study, or widely accepted off-label use of a device.
 - viii. Supporting documentation that is relevant or helpful (e.g. case report from another institution, abstract, or other data supporting the proposed intervention).
4. The CMO and CFO review the proposed intervention, evaluating:
 - a. The appropriateness of the proposed intervention and the ethical risks for the patient, healthcare provider/s and organization.
 - b. The competencies of the individual and team in the management of care for both expected and unexpected outcomes related to the innovative intervention.
 - c. The capacity of JHS and the involved disciplines to perform the intervention and the ability to monitor outcomes and provide or arrange for post-intervention care.
 - d. Risks from a public, financial, and capacity perspective.
5. The CMO and CFO in collaboration with the JHS Office of Research Administration may consult the Institutional Review Board (IRB) for further review if they deem it necessary in determining if the innovative therapy is appropriate and safe.
6. The CMO and CFO make the final determination to approve or decline the use of the proposed intervention.

D. Consent

1. Prior to scheduling and administration of the innovative intervention, informed consent must be obtained from the patient.
 - a. Follow the standard clinical procedures for Specific Consent for Treatment described Section C(2)(v) in JHS Policy No. 150A - Informed Consent Process using the consent form that does not reference “research” but references purpose, procedures, contacts, costs, risks, benefits and alternatives.

E. Reporting

1. Adverse Event Reporting
 - a. Adverse events related to innovative therapeutic or diagnostic approaches must be reported in accordance with Jackson Health System’s Incident Reporting System and reported to the CMO.
 - b. As soon as practicable after an event occurs, an appropriate JHS staff member or healthcare providers’ patient care unit or involved department must complete an event report following the instructions in JHS Policy No. 105A - Managing Safety Events.



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- c. In addition, an incident report must be submitted by the requesting physician to the CMO within 72 hours of occurrence.
 2. Serious Adverse Event Reporting (SAE)
 - a. SAEs must be reported to the CMO within 24 hours by the attending proposing the intervention and simultaneously reported in accordance with JHS Policy No. 105A - Informed Consent Process and placed in Jackson Health System's Incident Reporting System.
 3. Follow-up Reporting on the Outcome
 - a. A report on the outcome of the innovative therapy or procedure must be submitted to the Department head by the requesting physician within six months following approval.
 - b. A summary report on the outcome of the patients receiving the innovative therapeutic or diagnostic approach must be submitted to the CMO within one year following approval.
- F. Other Considerations
1. If the physician wishes to continue treating patients using this innovative therapeutic or diagnostic approach, he/she must file a request through the CMO, CFO, and Clinical Champions Committee requesting adoption of the innovative approach as a standard or acceptable therapy.
 2. Results of these cases may be published with prior written approval from CMO.

IV. References

1. Ayman Al Eyadhy, MD and Saleem Razack, MD. The Ethics of Using Innovative Therapies on the Care of Children., Paediatr Child Health. 2008 March; 13 (3); 181-184
2. Dale H. Cowan. American Bar Association, "Innovative Therapy versus Experimentation"; Tort & Insurance Law Journal, Summer 1986, Vol. 21, No. 4 (Summer 1986), pp. <https://www.jstor.org/stable/25761725>, p 619-633
3. <https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Innovative-Therapy-and-Diagnosis.pdf>
4. <https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html>
5. JHS Policy No. 105A - Managing Safety Events
6. JHS Policy No. 150A - Informed Consent Process
7. JHS Policy No. 805 - Adverse Events Involving JHS Study Subjects
8. 21 CFR 312.300

Responsible Party: Director, Clinical Research
JHS Clinical Trials Office

Reviewing Committee(s): JHS Policy & Procedure Committee
Chief Nursing Officer Council
Medical Executive Committee

Authorization: CEO, Jackson Health System